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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,421	SACKSTEIN, ROBERT	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/27/05; 11/25/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *8-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.
Applicant's submission filed on 11/25/05 has been entered.

2. Applicant's amendment, filed 7/27/05, has been entered.
Claims 1, 2 and 6 have been amended.
Claim 64 has been added.

Claims 8-61 have been withdrawn as being drawn to non-elected inventions.

Claims 1-7 and 62-64 are being acted upon as the elected invention. .

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's amendment, filed 7//27/05.
The rejections of record can be found in the previous Office Action.

4. Claims 1-7 and 62-64 are rejected under 35 U.S.C.§ 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

"A preparation of a substantially purified glycosylated CD44 polypeptide, said glycosylated CD44 polypeptide comprising an amino acid sequence encoded by a nucleotide sequence comprising exons 1-5, 16,18, and 20 of a human CD44 gene, and wherein the CD44 polypeptide is a human CD44H isoform, a human CD44R1 or a human CDR2 isoform, wherein said glycosylated CD44 polypeptide binds to an antibody having the binding specificity of monoclonal antibody HECA-452, and wherein the preparation comprises less than 30% of a polypeptide other than the glycosylated CD44 polypeptide" (see claim 1);
"CD44H isoform" (see claim 62),
"CD44R2 isoform" (see claim 63) and
"CD44R1 isoform" (see claim 64).

Applicant's arguments, filed 7/27/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

Although applicant has amended the claims to recite exons of human CD44 genes, such CD44 glycosylated polypeptides do not meet the written description provisions of 35 USC 112, first paragraph, essentially for the reasons of record.

Again, applicant argues that the relevant identifying characteristics of the claimed genus have been disclosed and that the exons and isoforms are known.

For example, applicant relies upon the binding specificity of the HECA-452 antibody which binds sialyated carbohydrate epitopes as a characteristic function of the claimed polypeptides.

However, the HECA-452 antibody binds sialyated carbohydrate epitopes on various molecules and tissues (e.g. HECA-452 antigen, CLA, Langerhan's cells) and is not restricted to CD44 polypeptides.- or to KG1a / CD44H or CD44R2 CD44 isoforms.

While it is acknowledged that applicant has disclosed certain specific species that fall in the broad genus of claimed CD44 isoforms, the claims are not limited to such specific sequences, but rather is broader in scope.

The claims do not recite and the instant specification does not provide sufficient written description as to the correlation between the chemical structure of CD44 isoforms and the function of the genus of CD44 isoforms.

For example, the HECA-452 antibody binds sialyated carbohydrate epitopes on various molecules and tissues (e.g. HECA-452 antigen, CLA, Langerhan's cells) and is not restricted to the particular CD44 isoforms recited in the claims. Further, single amino acid substitutions in a common allele can ablate binding of a monoclonal antibody and there is a dissociation of immunoreactivity from other biological activities when constructing analogs. Therefore, the reliance on the HECA-452 antibody is based upon an antibody that binds antigens and tissues other than featured by the instant KG1a / CD44H / CD44R1 / CD44R2 CD44 isoforms as well as reliance on known structures of the CD44 antigen to provide for antigens that lack the critical KG1a / CD44H / CD44R2 structural elements.

The instant claims provide insufficient functional attributes correlated to a structure that defines CD44 isoforms that features a glycosylated polypeptide expressed on normal human hemopoeitic progenitor cells and on leukemic blasts designated hemopoietic cell E-selectin/L-selectin ligand (HCELL), KG1aCD44, novel glycoform of CD44 containing HECA-452 reactive sialyated, fucosylated N-glycans, which is a ligand for both E-selectin and L-selectin (see Summary of the Invention).

Although page 9, paragraphs 2-3 of the specification discloses that a CD44H isoform is the most predominant form on hemopoietic cells, the claims are not limited to a single structure.

In addition, while applicant appears to rely on known or "standard or hematopoietic isoforms of CD44", applicant continues to try to distinguish the instantly claimed HCELL from other known CD44 glycoforms without necessarily claiming those distinguishing structural characteristics that are correlated to the particular functionals characteristics now claimed, other than the limited species disclosed in the specification as filed.

Although page 10, paragraph 3 of the specification discloses a CD44R1 and CD44R2 isoform, the actual structure of said CD44R2 isoform is not readily apparently.

Further, applicant has not provided a sufficient number of species to support a genus of CD44R1 and CD44R2 isoforms.

Given applicant's disclosure of identifying a particular KG1a / CD44 isoform, the reliance on the disclosed limited examples of the CD44 isoforms that features a glycosylated polypeptide expressed on normal human hemopoeitic progenitor cells and on leukemic blasts designated hemopoietic cell E-selectin/L-selectin ligand (HCELL), KG1aCD44, novel glycoform of CD44 containing HECA-452 reactive sialyated, fucosylated N-glycans, which is a ligand for both E-selectin and L-selectin in the specification as filed (see Summary of the Invention) does not support the written description of any such featured KG1a / CD44 isoform, as currently recited. The claims do not recite all of the relevant identifying characteristics such as structure of other physical and/or chemical characteristics that distinguishes the claimed KG1a / CD44 isoform (also (CD44H and CD44R2) from the genus of CD44 isoforms.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. The Court elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Again, it is acknowledged that the instant specification discloses certain KG1a CD44 isoforms, however, the claims are not limited to these particular KG1a CD44 isoforms and the claims not recite the critical identifying characteristic that defines each of these disclosed KG1a CD44 isoforms.

A person of skill in the art would not know which sequences or structural elements are essential, which sequences or elements are non-essential, and what particular sequence lengths identify essential sequences or what elements identify KG1a CD44 / CD44H / CD44R2, featured by the claimed invention.

In the absence of structural characteristics that are shared by members of the genus of featured KG1a / CD44 / CD4H / CD44R2 isoforms; one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Again, applicant is invited to amend the claims to recite all of the relevant identifying characteristics that define the featured KG1a CD44 / CD44H / CD44R2 isoforms.

5. Claims 1-7 and 62-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the particular KG1a / CD44 isoform that features a glycosylated polypeptide expressed on normal human hemopoeitic progenitor cells and on leukemic blasts designated hemopoietic cell E-selectin / L-selectin ligand (HCELL), KG1aCD44, novel glycoform of CD44 containing HECA-452 reactive sialyated, fucosylated N-glycans, which is a ligand for both E-selectin and L-selectin in the specification as filed (e.g., see Summary of the Invention and Detailed Description)
does not support the written description of any such featured KG1a / CD44 isoform, as currently recited.

Applicant's arguments, filed 7/27/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

Again, although applicant relies upon guidance for features required for functionality such as L-selectin and E-selectin ligand activity provided by the specification as filed and the disclosure of multiple species, it is maintained that the current claims are broader in scope than the particular KG1a / CD44H/ CD44R2 CD44 isoforms that are disclosed in the specification which are asserted to be distinguishable from the prior art CD44 isoforms.

Further, the clams do not recite the specific sequences associated with the particular CD44H and CD44R2 isoforms, as currently recited.

"A preparation of a substantially purified glycosylated CD44 polypeptide, said glycosylated CD44 polypeptide comprising an amino acid sequence encoded by a nucleotide sequence comprising exons 1-5, 16,18, and 20 of a human CD44 gene, and wherein the CD44 polypeptide is a human CD44H isoform, a human CD44R1 or a human CDR2 isoform, wherein said glycosylated CD44 polypeptide binds to an antibody having the binding specificity of monoclonal antibody HECA-452, and wherein the preparation comprises less than 30% of a polypeptide other than the glycosylated CD44 polypeptide" (see claim 1);
"CD44H isoform" (see claim 62),
"CD44R2 isoform" (see claim 63) and
"CD44R1 isoform" (see claim 64).

The claims do not recite all of the relevant identifying characteristics such as structure of other physical and/or chemical characteristics that distinguishes the claimed KG1a / CD44 isoform (also (CD44H and CD44R2) from the genus of CD44 isoforms (e.g. see Summary of the Invention and Detailed Description).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has not claimed sufficient biochemical information (e.g. amino acid composition, etc.) that distinctly identifies the asserted distinguishable Kg1a / CD44H / CD44R2 CD44 isoforms, other than those encompassed by the disclosure of the particular KG1a / CD44H / CD44R2 CD44 isoforms disclosed in the specification as filed (e.g. see Summary of the Invention and Detailed Description).

Applicant is relying upon certain asserted structural and functional activities and the disclosure of a limited representative number or a single species (e.g. CD44H, CD44R2) to support an entire genus of KG1a / CD44H / CD44R2 CD44 isoforms. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable a genus of KG1a CD44 isoforms that identify the featured KG1a / CD44H / CD44R2 CD44 isoforms disclosed in the specification that are asserted to be distinguishable from the prior art.

Since the amino acid sequence of a polypeptide, and, in turn, a KG1a CD44 / CD44H/ CD44R2 polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence or which changes in structural elements and still retain similar functionality (e.g. ligand for both E-selectin and L-selectin) or expression (e.g., normal human hemopoeitic progenitor cells and on leukemic blasts designated hemopoietic cell E-selectin/L-selectin ligand (HCELL)) requires a knowledge of and guidance with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which a polypeptide's structure (and, in turn, a distinguishable KG1a / CD44H / CD44R2 CD44 isoform) relates to its functional usefulness. However, the problem of predicting polypeptide structure from limited or a single species and, in turn, utilizing predicted structural determinations and finally what changes can be tolerated with respect thereto is complex and well outside the realm of routine experimentation. In re Fisher, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Ngo et al.; in The Protein Folding Problem and Tertiary Structure Prediction,1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.) and Skolnick et al. (Trends in Biotech. 18: 34- 39, 2000) are of record.

While it is acknowledged that applicant has disclosed certain specific species that fall in the broad genus of claimed CD44 isoforms, the claims are not limited to such specific sequences, but rather is broader in scope.

The claims do not recite and the instant specification does not provide sufficient enablement as to the correlation between the chemical structure of CD44 isoforms and the function of the genus of CD44 isoforms. For example, the HECA-452 antibody binds sialyated carbohydrate epitopes on various molecules and tissues (e.g. HECA-452 antigen, CLA, Langerhan's cells) and is not restricted to the particular CD44 isoforms recited in the claims.

Further, single amino acid substitutions in a common allele can ablate binding of a monoclonal antibody and there is a dissociation of immunoreactivity from other biological activities when constructing analogs. Therefore, the reliance on the HECA-452 antibody is based upon an antibody that binds antigens and tissues other than featured by the instant KG1a / CD44H / CD44R2 CD44 isoforms and the reliance on 95% identity and alternative splicing of the CD44 antigen provides for antigens that lack the critical KG1a / CD44H / CD44R2 structural elements.

The instant claims provide insufficient functional attributes correlated to a structure that defines CD44 isoforms that features a glycosylated polypeptide expressed on normal human hemopoeitic progenitor cells and on leukemic blasts designated hemopoietic cell E-selectin/L-selectin ligand (HCELL), KG1aCD44, novel glycoform of CD44 containing HECA-452 reactive sialyated, fucosylated N-glycans, which is a ligand for both E-selectin and L-selectin (see Summary of the Invention).

Although page 9, paragraphs 2-3 of the specification disclose that a CD44H isoform is the most predominant form on hemopoietic cells, the claims are not limited to a single structure (e.g. SEQ ID NO).
In addition, the specification appears to indicate that there are multiple forms of CD44 by disclosing there is a "standard or hematopoietic isoform of CD44.

Although page 10, paragraph 3 of the specification discloses CD44R1 and CD44R2 isoforms, the actual structure of said isoforms is not readily apparent.

Further, applicant has not provided a sufficient number of species to support a genus of CD44R and CD44R2 isoforms.

Because of the lack of sufficient guidance and predictability in determining which structures would lead to the identification of the featured KG1a / CD44H / CD44R1 / CD44R2 CD44 isoforms of the instant invention and asserted to be distinguishable from other CD44 isoforms with the disclosed properties and the relationship between the critical distinguishing structural elements of said KG1a / CD44H / CD44R1 / CD44R2 CD44 isoforms was not well understood and was not predictable; it would require an undue amount of experimentation for one of skill in the art to arrive a genus of the instant featured KG1a / CD44H CD44R1 / CD44R2 CD44 isoforms that are distinguishable from other CD44 isoforms. The instant specification provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement in that will enable any person skilled in the art to make and use the invention

Without sufficient guidance, making and using a genus of the featured and distiguishable KG1a / CD44H CD44R1 / CD44R2 CD44 isoforms broadly encompassed by the claimed invention would have been unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Applicant's arguments are not found persuasive.

6. Claims 1-7 and 62-64 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62-63 are indefinite in the recitation of "CD44H", "CD44R1" and "CD44R2" in that they only describe the products of interest by an arbitrary protein name. While the name itself may have some notion of the activity of the protein, there is nothing in the claims which distinctly claims the polypeptide. Applicant should particularly point out and distinctly claim the "CD44", "CD44R1" and "CD44R2" by claiming sufficient characteristics associated with the protein (e.g. amino acid composition). Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is and what the compositions are made up of.

The instant claims do not recited all of the identifying properties or combination of properties which are unique to and, therefore, definitive of either "CD44", "CD44R1" and "CD44R2", in turn, an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

Applicant's arguments, filed 7/27/05, have been fully considered but are not found convincing essentially for the reasons of record.

Although applicant argues that the terms are known, the claims recite "a" "CD44", "CD44R1" and "CD44R2" isoform, indicating multiple forms and variations. Therefore, in contrast to applicant's arguments, the metes and bounds of said isoforms are ill-defined and ambiguous as to whether they read on a particular structure / molecule or multiple structures and variations on multiple molecules.

Applicant's arguments are not found persusive.

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. ♣§ 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7 and 62-64 are rejected under 35 U.S.C. § 102(a) as being anticipated by Dimitroff et al. (PNAS 97: 13841-13846, 2000) (1449; #AI) (see entire document).

Dimitroff et l. teach the distinct glycoform of CD44 on human hemopoietic cells, including KG1a cell line, wherein the HCLL-CD44 taught by the reference has the same structural and functional characteristics of the instantly claimed and disclosed HCLL.

9. Claims 1-7 and 62-64 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sackstein et al. (Blood 89: 2773 – 2781, 1997), as further evidenced by Dimitroff et al. (J. Biol. Chem. 276: 47623 – 47631, 2001) and Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004).

Applicant's arguments, filed 7/27/05, have been fully considered but aren ot found convincing essentially for the reasons of record.

It appears that applicant is simply asserting that Sackstein does not state the claimed limitations, yet provides no objective evidence that this prior art by the inventor Sackstein teaching the same HCELL somehow is different from that claimed and disclosed in the instant application.

In contrast to applicant's assertions, it is the inventor Sackstein who teaches the hemopoietic cell L-selectin ligand which exhibits sulfate-independent binding activity that appears to be the same KG1a CD44 glycosylated polypeptide of the claimed invention (see entire document, including Abstract, Results and Discussion). Further, the Discussion describes the Results and the characterization of same KG1a CD44 isoform of the instant invention, including the nature of the sulfation-dependent epitope (see pages 2779-2780 of the Discussion)

In further evidence, Dimitroff et al. discloses that the L-selectin ligand disclosed in Sackstein et al. (Blood 89: 2773 – 2781, 1997) reads on the instant hemopoietic cell E- and L-selectin ligand (see reference 18 cited in the Introduction, particularly page 47623, column 2, paragraph 1).

Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004) has been added as further evidence that the claimed HCLL is not novel or new.

"although initially considered to be a novel selectin ligand bythe above biochemical criteria, mass spectrometry subsequently revealed that HCELL is not novel per se: it is a glycoform of a well-recognized integral membrane glycoprotein, CD44, that expresses the CLA epitope."

See page 1064, column 1, paragraph 1 of Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004).

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

As set forth in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999):
AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art=s functioning, does not render the old composition patentably new to the discoverer. A The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

Given the PTO's inability to manufacture products or to obtain and compare prior art products, the examiner properly shifted burden to applicant to establish, through objective evidence, that the very same KG1a CD44 polypeptide described by the inventor in by Sackstein et al. (Blood 89: 2773 – 2781, 1997), as well as by the inventor in the Dimitroff et al. (J. Biol. Chem. 276: 47623 – 47631, 2001). Thre is insufficient objective evidence that distinguishes the same or nearly the same KG1a CD44 isoforms in the prior art by the inventor from those CD44 isoforms currently encompassed by the instant claims.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01(C).

Sackstein et al. teach the hemopoietic cell L-selectin ligand which exhibits sulfate-independent binding activity that appears to be the same KG1a CD44 glycosylated polypeptide of the claimed invention (see entire document, including Abstract, Results and Discussion).

In further evidence, Dimitroff et al. discloses that the L-selectin ligand disclosed in Sackstein et al. (Blood 89: 2773 – 2781, 1997) reads on the instant hemopoietic cell E- and L-selectin ligand (see reference 18 cited in the Introduction, particularly page 47623, column 2, paragraph 1).

Applicant's arguments have not been persuasive.

10. Claims 1-7 and 62-64 are rejected under under 35 U.S.C. 102(b) as being anticipated by Stamenkovic et al. (EMBO Journal 10: 343 –348, 1991) (see entire document, including Figure 1) as evidenced by Sackstein (US 2003/0040607 A1) and Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004).essentially for the reasons of record.

Applicant's arguments in conjunction with the Sackstein Declaration under 37 CFR 1.132, filed 7/27/05, have been fully considered but are not found convincing essentially for the reasons of record.

Although applicant argues that the reference teaches only expression by those cells such as COS or Namalwa that would not express HCELL,
The reference is *not* limited to expression by such cells.

Stamenkovic et al. teach the expression of CD44 transcripts in primary tumors of mesenchymal and epithelial origin, in normal epithelium and in lymphocytes (see page 344, column 1, paragraph 1 and Figure 2 as well as pages 345-346).

Also, Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004) has been added as further evidence that the claimed HCLL is not novel or new.
"although initially considered to be a novel selectin ligand bythe above biochemical criteria, mass spectrometry subsequently revealed that HCELL is not novel per se: it is a glycoform of a well-recognized integral membrane glycoprotein, CD44, that expresses the CLA epitope."
See page 1064, column 1, paragraph 1 of Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004).

Therefore, as pointed out previously and in contrast to applicant's assertions, Stamenkovic et al. teach hemopoietic and epithelial forms of CD44, including encoding nucleotide and amino acids of CD44, which appear to be the same or nearly the same as the instant hemopoietic cell L-selectin / E-selectin ligand (HCELL), also referenced to as KG1a CD44, which is a glycoform of CD44 and comprising SEQ ID NO: 1, as set forth in Sackstein (US 2003/0040607 A1; see entire document, including Summary of the Invention, Examples, Table 1 and Claims).

Given the teaching of the structural characterization (e.g. amino acid and encoding nucleic acids) of CD44 isoforms as well as hemopoietic source of said CD44 isoforms (e.g CD44H referenced in Stamenkovic et al.) which is consistent with the instant disclosure as well as applicant's publication Sackstein (US 2003/0040607 A1) as well as the breadth of the instant claims, the prior art appears to read on the claimed polypeptides, in the absence of objective evidence to the contrary.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

As set forth in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999):
"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

The PTO's inability to manufacture products or to obtain and compare prior art products. Examiner properly shifted burden to applicant to establish, through objective evidence, that the very same KG1a CD44 polypeptides, including hemopoietic derived CD44 isoforms comprising SEQ ID NO: 1 described by Stamenkovic et al. and consistent with the teachings of the instant application and inventor's publication Sackstein (US 2003/0040607 A1), currently encompassed by the instant claims.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01(C).

Applicant's arguments are not found persuasive.

11. Upon the abandonment of USSN 09/619,290, the previous provisional rejection under the judicially created doctrine of obviousness –type double patenting has been withdrawn.

12. No claim allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
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